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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
10/081,885	02/20/2002	Stephen J. Kaufman	94-00	9945

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GREENLEE WINNER AND SULLIVAN P C
5370 MANHATTAN CIRCLE
SUITE 201
BOULDER, CO 80303

EXAMINER
HADDAD, MAHER M

ART UNIT	PAPER NUMBER
1644	9

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Application No.	Applicant(s)
10/081,885	KAUFMAN, STEPHEN J.
Examiner	**Art Unit**
Maher M. Haddad	1644

Office Action Summary

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4)☐ Interview Summary (PTO-413) Paper No(s). _____
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-3, drawn to a method of identifying an individual exhibiting symptoms of a muscular dystrophy comprising obtaining a tissue sample from the individual which is known in a normal individual to express $\alpha 7\beta 1$ and determine the level of the translation of the $\alpha 7\beta 1$ integrin using an antibody, classified in Class 435, subclass 7.1.

II. Claims 1 and 4-6, drawn to a method of identifying an individual exhibiting symptoms of a muscular dystrophy comprising obtaining a tissue sample from the individual which is known in a normal individual to express $\alpha 7\beta 1$ and determine the level of the transcription of the $\alpha 7\beta 1$ integrin using reverse transcriptase-polymerase chain reaction, classified in Class 435, subclass 6.

III. Claims 7-12, drawn to a reporter gene construct comprising a transcription regulatory sequence of a human $\alpha 7$ integrin gene and a reporter coding sequence; classified in Class 536, subclasses 23.1.

IV. Claims 13-14, drawn to a method for identifying a composition which increases expression of an $\alpha 7$ integrin gene comprising contacting a host cell comprising the reporter gene construct with test composition, classified in Class 435, subclass 6.

V. Claims 15-16, drawn to a method of alleviating symptoms of a muscular dystrophy which is characterized by levels of $\alpha 7$ integrin comprising administering to a patient suffering from or susceptible to the muscular dystrophy a composition; classified in Class 514, subclass 2.

VI. Claims 17-23, drawn to a method of alleviating symptoms of a muscular dystrophy which is characterized by levels of $\alpha 7$ integrin, dystrophin and or utrophin comprising administering to a patient suffering from or susceptible to the muscular dystrophy a DNA construct comprising an $\alpha 7$ integrin; classified in Class 514, subclass 44.

2. Groups I-II and IV-VI are different methods. A method of identifying and a method of alleviating differ with respect to ingredients, method steps, and endpoints; therefore, each method is patentably distinct.

3. Groups III and VI are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the reporter gene construct of Group IV can be used for quantitatitve imaging, in addition to the methods of alleviating recited.

4. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by different classification and or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods of use comprising distinct method steps. Therefore restriction for examination purposes as indicated is proper.

Species Election

5. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

A. If Group III is elected, applicant is required to elect a reporter gene construct comprising a transcription regulatory sequence of a human α7 integrin gene and a reporter coding sequence, wherein the reporter coding sequence is a) a green fluorescent protein, b) luciferase, c) β-lactamase, d) β-glactosidease, e) β-glucuronidase or f) an immunological tag protein. These are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

B. If Group VI is elected, applicant is required to elect a method of alleviating symptoms of a muscular dystrophy, wherein the vector sequence is a) a virus vector sequence or b) a plasmid sequence. These are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (703) 306-3472. The examiner can normally be reached Monday through Friday from 8:00 AM to 4:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Maher Haddad, Ph.D.
Patent Examiner
Technology Center 1600
February 10, 2003

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600